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REMARKS

I. Claim Rejections – 35 U.S.C. §112

Claims 3-16 and 27-32 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The expression “substantially uncrosslinked” is alleged to render claims 3-8 indefinite. Applicants respectfully disagree.

Nevertheless, to advance the application to allowance, the expression “substantially uncrosslinked” has been deleted from claims 3-8.

Withdrawal of the §112 rejection is requested.

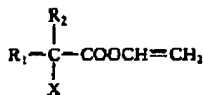
II. Claim Rejections – 35 U.S.C. §103

a. claims 3-6 and 31

Claims 3-6 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over US 4,056,497 to Reinecke et al. (“Reinecke”) in view of US 3,944,513 to Greenwald et al. (“Greenwald”).

Reinecke discloses a process for the preparation of an aqueous copolymer dispersion capable of being cross-linked in the presence of alkalis by polymerization of a mixture of monomers. The specific monomers are disclosed at column 1, line 57, to column 2, line 32, of Reinecke:

- a. 60 to 95% by weight, calculated on the monomer mixture, of at least one acrylic acid ester and/or methacrylic acid ester of a saturated aliphatic alcohol having from 1 to 20 carbon atoms,
- b. 0 to 40% by weight, calculated on the monomer mixture, of monomers the homopolymers of which have second order transition temperature of from -40°C to +150°C,
- c. 0.1 to 10% by weight, calculated on the monomer mixture, of an α -haloalkane carboxylic acid vinyl ester of the formula (I)

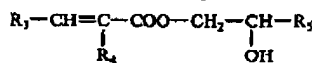


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wherein R_1 and R_2 each represents hydrogen or an alkyl radical having from 1 to 5 carbon atoms and X is fluorine, chlorine, bromine or iodine,

d. 0.1 to 10% by weight, calculated on the monomer mixture of, α,β -ethylenically unsaturated carboxylic acids having from 3 to 8 carbon atoms or their partial ester with saturated aliphatic alcohols having from 1 to 20 carbon atoms and

e. 0 to 10% by weight, calculated on the monomer mixture, of monomers containing hydroxyl groups and having the formula (II)



wherein R_3 is hydrogen, a methyl group or the group $-\text{COOR}_6$, R_4 and R_5 each is hydrogen or a methyl group and R_6 is hydrogen or an alkyl group having from 1 to 12 carbon atoms.

(col. 1, line 57, to col. 2, line 32)

Reinecke neither discloses nor suggests the claimed invention for the following two reasons:

- Firstly, Reinecke requires the presence of the activated halogen compound (c) and the α,β -ethylenically unsaturated carboxylic acids (d). Each of reactive monomers (c) and (d) must be present in an amount 0.1-10% by weight. As disclosed and claimed, the monomer mixture of the claimed invention does not include reactive monomers (c) and (d). Furthermore, Applicants submit that the inclusion of reactive components (c) and (d) of Reinecke would offset the chemical interaction among the monomers of the claimed invention with a reasonable expectation that the antisticking properties of the resulting copolymer/dispersion would be different from those which are observed with the claimed invention.
- Secondly, the claims expressly provide that the claimed aqueous film coating dispersion is substantially free of residual emulsifying agent. Reinecke discloses that the prior art aqueous dispersion is prepared by free radical polymerization using emulsifiers, protective colloids and, optionally, regulators. However, Reinecke does not disclose, either expressly or inherently, that the emulsifying agent is partially or fully removed

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after polymerization. On page 4 of the final Office Action, the Examiner acknowledges that Reinecke is silent about the removal of the emulsifier.

To overcome the deficiencies of Reinecke to disclose or suggest the claimed invention, the Examiner relies on the secondary reference to Greenwald which is directed to methods of purifying aqueous polymer dispersions of particulate vinyl polymers prepared by emulsion polymerization. In the background section of the secondary reference, Greenwald refers to emulsifiers as an example of an impurity of an aqueous dispersion of vinyl polymers (See col. 1, line 17). Yet at column 1, lines 44-49, Greenwald suggests that the removal of emulsifiers from such dispersions by earlier methods may have actually contributed to coagulation. However, it is at column 1, lines 44-49, that Greenwald gives the clearest and most unequivocal teaching against the removal of emulsifiers from the dispersion with the Greenwald method:

The capacity for adsorbed materials, as well as selectivity for given impurities *as against materials desirably left in the dispersion such as emulsifiers* and dispersants, and as against water are in part dependent upon surface area, pore size, water wettability, total pore volume, and surface polarity or degree of oxidation of the surface. (Emphasis added)

It cannot be disputed. While Greenwald may provide a method for removing selective impurities, it is unequivocal that Greenwald teaches the *desirability* of leaving the emulsifier in the dispersion after the polymerization reaction. As such, Greenwald teaches against the claimed invention. Accordingly, there would have been no motivation at the time the claimed invention was made to combine Reinecke and Greenwald to arrive at the claimed invention. For all of the foregoing reasons, therefore, a *prima facie* case of obviousness has not been established. Withdrawal of the §103 rejection based on the combination of Reinecke and Greenwald is requested.

b. claims 9-14

Claims 9-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in view of Greenwald and US 5,055,306 to Barry et al. ("Barry").

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Barry is directed to a sustained-release formulation in the form of effervescent or water-dispersible tablets (col. 1, lines 5-7). In the paragraph bridging columns 4 and 5, it is stated that "sustained-release formulations of pharmacologically active substances have not previously been presented, or at least successfully presented, in the form of effervescent or water-dispersible tablets". To solve this problem, Barry discloses a specific coating covering substantially the whole surface of a core containing granules of a pharmaceutically active and effervescent or water-dispersible ingredients. As disclosed at column 3, lines 48-53, the coating comprises the following: 100 parts of a water insoluble but water swellable acrylic polymer, and from 20 to 70 parts of a water soluble hydroxylated cellulose derivative.

Each of the rejected claims 9-14 is dependent, either directly or indirectly, on any one of claims 3-8. Specifically, the invention of claims 9-14 is characterized by a film coating that is prepared by applying the aqueous polymer dispersion of claims 3-8 that is prepared by the polymerization of a monomer mixture to obtain an aqueous film coating dispersion that is substantially free of residual emulsifying agent which is removed after the polymerization reaction.

It is evident that Barry fails to overcome the deficiency of the combination of Reinecke and Greenwald to suggest the claimed aqueous film coating dispersion. For all of the reasons discussed in Section II(a), above, it is submitted that a *prima facie* case of obviousness has not been established. The combination of the Reinecke, Greenwald or Barry, whether taken alone or in combination, does not suggest the claimed invention. Nor would the cited combination result in the claimed invention. Withdrawal of the §103 rejection of claims 9-14 is requested.

c. claims 15 and 16

Claims 15 and 16 are rejected under 35 U.S.C. §103(a) as being unpatentable over the combined teaching of Reinecke, Greenwald, Barry, US 5,939,578 to Chen ("Chen") and US 4,957,745 to Jonsson et al. ("Jonsson").

Claims 15 and 16 are directed to the active ingredients of the claimed pharmaceutical formulation. The Examiner notes that Barry does not teach the beta-blocking adrenergic agent to be metoprolol salts such as tartrate, succinate, fumarate or benzoate salt. For this purpose, the Examiner relies on Chen and Jonsson.

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Claims 15 and 16 are dependent on claim 14 which is itself indirectly dependent on any one of claims 3-8. The patentability of claim 14 is discussed in the preceding Section II(b), above. Applicants submit that neither Chen nor Jonsson overcomes the failure of the combination of Reinecke, Greenwald and Barry to render the pharmaceutical formulation of claims 15-16 obvious for the reasons given in Section II(b), above. A *prima facie* case of obviousness has not been established. Withdrawal of the §103 rejection of claims 15 and 16 is requested.

d. claims 27-30 and 32

Claims 27-30 and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in combination with Greenwald, US 6,646,046 to Contrada et al. ("Contrada") and GB 1 141 165 ("Zellstoffwerke").

With respect to the limitations of dependent claims 27-30 and 32, the Examiner acknowledges that Reinecke does not teach the repeating units in component (e), i.e., Formula II, and an alkoxy group with C1-20 for the terminal group. For this purpose, the Examiner relies on Contrada and Zellstoffwerke.

Contrada is directed to an aqueous pressure-sensitive adhesive composition. The Examiner relies specifically on the disclosure of the monomer M₁ disclosed at column 3, lines 38-54. Zellstoffwerke is directed to the manufacture of acrylic films. The Examiner relies on the disclosure by Zellstoffwerke of an ester of a polyethoxylated product containing at least one acrylic or methacrylic ester group. The Examiner alleges that the cited compounds of Contrada and Zellstoffwerke, respectively, encompass component (e) of Reinecke.

Each of claims 27-30 and 32 is directly dependent on claim 4, 6 or 8. It has been established in the preceding Section II(a), above, that the combination of Reinecke and Greenwald does not render obvious the claimed aqueous film coating dispersion. Applicants submit that neither Contrada nor Zellstoffwerke overcomes the failure of Reinecke in combination with Greenwald to render the pharmaceutical formulation of claims 4, 6 or 8 obvious for the reasons given in the preceding Section II(a), above. A *prima facie* case of obviousness has not been established. Withdrawal of the §103 rejection of claims 27-30 and 32 is requested.

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e. claims 7 and 8

Claims 7 and 8 are rejected under 35 U.S.C. §103(a) as being unpatentable over US 3,875,099 to Kurth et al. in view of US 3,890,292 to Bohme et al. as evidenced by US 5,626,655 to Palowowski et al., US 4,101,490 to Pons et al. and "Polymer Technology Dictionary" by Tony Whelan.

The obviousness rejection has been rendered moot by the amendment of claims 7 and 8 which are now dependent on claims 3 and 4, respectively. Furthermore, amended claims 7 and 8 recite that the emulsifying agent is the surfactant, or monomer of the formula I, which acts as the emulsifier during the polymerization reaction. Support is found at page 7, lines 15-24, and page 10, lines 20-21. Applicants submits that amended claims 7 and 8 are patentable for the reasons given in Section II(a), above.


CONCLUSION

Applicants submit that the claim amendments and remarks are a good faith attempt to be fully responsive to the Office Action. In view of the claim amendments and remarks herein, the application is in condition for allowance.

Authorization is hereby given to charge any fee due in connection with this Amendment to Deposit Account No. 23-1703.

Dated: 2 December 2008

Respectfully submitted,


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